Statement of

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## Committee on Government Reform

## United States House of Representatives

Hearing on

## Reduced Exposure/Reduced Risk Tobacco Products: An Examination of the Potential Public Health Impact and Regulatory Challenges

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Thank you for the opportunity to testify on the issues and opportunities raised by the diversity of nicotine delivery systems that have been marketed or are in development. There are surely few other areas of health in which there are actions that could be taken by the Congress and regulatory agencies that have such great potential to either improve or harm public health. I will focus on the questions posed in my invitation to testify.

**Basis for Testimony**

I am speaking on my own behalf and not as a representative of the organizations, of which I am a member, consult for, or serve. I am Professor of Behavioral Biology (Adjunct), Department of Psychiatry, The Johns Hopkins University School of Medicine, and Vice President for Research and Health Policy, Pinney Associates. I was trained in behavioral science, pharmacology, and other disciplines relevant to understanding drug addiction and have focused on tobacco-related issues for 25 years. From 1980 to 1996, I directed tobacco and other drug research at the National Institute on Drug Abuse (NIDA). While at NIDA, I was the primary liaison to the FDA on tobacco products and tobacco addiction treatment. I contributed to numerous Surgeon General's reports as well as reports by other agencies. I am past president of the Society for Research on Nicotine and Tobacco and have served on national and international committees addressing the challenges posed by the plethora of nicotine delivery systems that have been marketed or are possible. I presently serve on the World Health Organization (WHO) Scientific Advisory Committee on Tobacco Product Regulation. I am a recipient of a Robert Wood Johnson Foundation Innovators Award and presently am director of this program which is intended to recognize and foster innovations to reduce substance abuse and addiction in America.

**Fundamental facts**

*Tobacco addiction* is the most pernicious and persistent of all forms of drug addiction leading the majority of users to deadly daily use with 50% of continuing smokers prematurely dying of smoking caused disease. Nonetheless, with support and encouragement many tobacco users can achieve freedom from tobacco and dramatically improve their chances of longer, healthier, and more productive lives. Others need treatment to achieve these goals and increased treatment access has helped millions of Americans quit smoking and other forms of tobacco use.

*Smoking cessation* is accompanied by rapid and significant reductions in risk of heart disease, as well as reduced risk of lung cancer and other diseases over time. The earlier in life that lasting tobacco cessation is achieved, the greater the benefits. Cessation also benefits non smokers, children in particular, who suffer far higher rates of asthma, respiratory infections, and sick days when they are exposed to smoke. In fact, when parents quit smoking their children are half as likely to start smoking and twice as likely to try to quit smoking if they have already begun. The lesson is clear: adult cessation and youth prevention go hand in hand.

*Comprehensive tobacco control* efforts based on solid public health principles reduce tobacco use and save lives. With increased education, tobacco costs, restrictions on

smoking, and access to treatment, more smokers are quitting than ever before. On a parallel front, although youth tobacco use remains unacceptably high, adolescent smoking and smokeless tobacco use has steadily declined in the past 3-4 years. From a public health perspective these trends are precious and encouraging, they spell improved health for millions of Americans in the near term and in future generations. We must be very careful to do nothing to reverse these trends.

*Exposure reduction products* could save lives or cost lives. What about people who are unable to completely give up tobacco? Could we reduce their risk of disease with products that are less poisonous? This was the premise of the Federal Trade Commission (FTC) approach to encouraging the development and use of reduced tar and nicotine cigarettes beginning in the 1960s. This was also the implied premise of smokeless tobacco marketing to high school and college athletes beginning in the 1970s. Of course motivation of FTC was to enable disease reduction whereas the motivation of tobacco companies was to grow their markets. Nonetheless, both experiments on the American people were health disasters as documented in reports of the Surgeon General, the Institute of Medicine, and National Cancer Institute. Both experiments went awry for decades before independent researchers – not the companies that were marketing the products – revealed the extent of the damage.

*Light cigarettes* delayed quitting and supposedly safer smokeless tobacco was a magnet for athletes who had been considered at low risk for any form of tobacco use prior to the healthy image product marketing of the 1970s. This experience, although sobering, should not discourage our nation from making progress on all fronts to reduce tobacco caused disease but it is a stark reminder that unintended consequences are a mine field that should be negotiated with supportive science and regulatory oversight. This is the core path articulated in the 2000 Institute of Medicine report on the topic and this is the core path that I support as a rational one towards improved health in America.

**The spectrum of nicotine delivery products – FDA regulation makes a difference**
Since 1985, nicotine gum has been available as an FDA approved smoking cessation aid This product has been joined by a slowly increasing number of additional forms of FDA approved Nicotine Replacement Therapy (NRT) products including patch, nasal spray, oral inhaler, and lozenge. Each product differs in form, dosing, side-effects, and instructions for smoking cessation. Determining the conditions of safe and effective use and then overseeing labeling and marketing to minimize unintended consequences such as situational use for the purpose of avoiding smoking cessation, misuse by children, and providing special guidance for youth, pregnant women, and persons with heart disease, is a science guided process overseen by FDA.

In the vacuum of FDA regulation for non medicinal nicotine products, the 19$^{th}$ century days of snake oil have re-emerged with vengeance since FDA was rebuked by the Supreme Court in 2000. Correctly gauging FDA's reluctance to act, companies, big and small, have unleashed new products every 3-4 months with no sign of letting up. These include the nicotine delivery devices "heated" by carbon fuel and electronic ignition systems, a "Tic Tac"-like tobacco lozenge", and smokeless tobacco products marketed to

help smokers remain smokers by using slogans such as "Any Time Any Where"™ and for "When You can't smoke."™ There are cigarettes implying safety with claims of "reduced carcinogens", "the next best thing to quitting," "80% less second hand smoke", and one with a misleading claim of "nicotine free" that is marketed for quitting by imitating the three step program of nicotine patches. By internet, there are nicotine lollipops (complete with "lollipop luggage"), nicotine water, and most recently, nicotine wafers.

Some of these products are placed next to FDA approved cessation aids in drug stores and have websites amounting to virtual versions of the old horse drawn patent medicine carts. None of these products have clinically tested and approved protocols for dosing, guidance for use to achieve health benefits (even where health benefits are implied) or guidance to minimize unintended consequences or dangerous forms of use (such as dual use to perpetuate smoking). Absent meaningful regulation, absent a science foundation, Americans are the guinea pigs for these products.

Yet, it is theoretically possible that some of these products could be useful to help people quit smoking. Some might be useful advances towards less deadly tobacco products for those who are unable to quit tobacco altogether. Presently there is no way for the consumer to know. There is no way for public health officials to know. There is no way for Congress to know. Yet, there is a rather straightforward path to this end. It is the path of scientific study and FDA regulation built around the key principle or pre-market evaluation of the products and the claims. It is a proven path towards products that are less harmful and possibly even helpful.

**Regulation can stifle or foster the treatment pipeline**

FDA regulation of medications is the world's premier model for pre-market approval of safe and effective medicines, as well as maintaining safe and usefully labeled food. Some of its most striking successes are the result of flexible adaptation of its authorities to foster drug development such as helping lead the world away from the view of AIDs as a death sentence to the understanding that AIDs is increasingly a manageable disease.

*One size does not fit all:* Unfortunately with respect to tobacco treatment products, the FDA approach has not kept pace with public demand or potential treatment developments. Tobacco users want and need increasingly flexible products to meet their diverse needs on the road to tobacco cessation. Yet at present, all products are approved based on the same 6 week cessation model that has served for nearly two decades, and the labeling has been homogenized to the point that consumers and health professionals alike do not understand how the different product forms may address differing needs. Worse, overly harsh labeling results in ironies such as people removing patches so they can "safely" smoke cigarettes.

*So much more is possible.* Medications could be used to reduce smoke exposure on the road to complete cessation but FDA inflexibility has left such applications on shelves. With support from the National Institute on Drug Abuse, small developers have made great progress on "vaccine-like" long acting medicines that could help former tobacco

users remain tobacco free the rest of their lives but this may require an entirely new model for evaluating efficacy. One developer is even working on a nicotine water based cessation aid – but there will be little incentive to properly evaluate it, develop clinically tested guidance, and obtain FDA approval if people can already get an untested version by Internet from a company that has dodged FDA oversight.

If FDA does not become more actively engaged and more flexible in the application of its authorities to treatment development and approval, the most innovative approaches will never see the light of day or will be so constrained that they will be irrelevant to public health. Without lowering its standards for safety and efficacy, FDA could give notice that it will consider application of its fast track and expedited review authorities that have been so successful in jumpstarting the pipeline of medicines for treating AIDS and cancer. FDA could give notice that it will consider a broader range of science based indications and claims shown to be desired and helpful to tobacco users. In short, FDA has existing authorities that could unleash improvements in treatment appeal, diversity, and availability. It just needs to apply them appropriately and flexibly.

**Federal efforts by CDC and NIH in particular have made a difference but could do much more**. It is in the interest of the federal government to support greater access and appropriate use of treatments that are approved by the FDA as well as those that are not under FDA jurisdiction but have been found to be effective by the US Public Health Service, such as behavioral therapies and alternative medications to meet the diversity of needs. Such treatments are among the most cost-effective of all treatments in health care, especially when compared to the enormous costs of treatments for the consequences of smoking such as cancer chemotherapies.

More fundamentally, it is in the interest of striving toward a healthy and productive America in which preventing unnecessary disease by tobacco is valued as highly as preventing auto accidents, and bioterrorism. Remember the basic numbers: 2000-3000 new tobacco users every day and more than 1000 preventable tobacco deaths every day as far as the epidemiologic eye can see. Should freedom from this preventable cause of death and disease be any less valued than freedom from other causes of disease? Perhaps most important to consider is that this area of public health is one in which many core principles have been established, tested and found effective.

While we do not have all the answers, recent progress following the application of tobacco control policies nationally and even more intensively in states such as California and Massachusetts is more impressive than many of us had dared hope for. A recent set of recommendations developed by the Subcommittee on Cessation by the Interagency Committee on Smoking and Health outlines a plan that is predicted to prevent at least three million premature deaths in existing smokers, and help an additional five million Americans quit smoking within one year. I support full adoption of the recommendations of this special report to the Secretary Thompson. Furthermore, any progress towards the goals articulated in the report would be steps in the right direction.

**Tobacco products that genuinely reduce risk merit serious consideration for inclusion in comprehensive tobacco control strategies but should be positioned so as to not undermine approaches that work.** I have served on many committees in the US and for the World Health Organization that take seriously the concept that every effort should be made to reduce tobacco toxin exposures to those who continue to use tobacco. It is evident that tobacco products are made more deadly than is technically and commercially feasible and that performance standards could be developed to establish maximum allowable levels of various toxins.

It is also recognized that effective regulation is critical. Without it, such an approach could do more harm than good. This is because how a product is used is as important how it is made when it comes to health effects. Regulation can guide how it is made, marketed, and used and provide a mechanism for corrective actions so that we never again need wait for several million deaths as we did from light cigarettes before recognizing unintended consequences. Regulation of tobacco and medications to treat dependence must be a coordinated process. Otherwise we will perpetuate the situation in which snake oil is increasingly at the doorstep in ever more attractive iterations, while proven safe and effective treatments and strategies that could save lives die in development.

**Dr. Koop's advice:** ***Be appropriate and flexible.*** In conclusion, I urge the Committee to consider the wisdom of former Surgeon General C. Everett Koop whose testimony in support of over the counter marketing of nicotine gum and patches I paraphrase: *It is easy to get the disease and hard to get treatment, as a nation we must work to reverse this. Over-the-counter marketing is a step in the right direction.* Remarkably and presciently, FDA granted this approval in the same year that it issued its rule to regulate tobacco products and restrict tobacco product marketing. Time has proved that FDA was on target from the perspective of science and health. We need to get back on track. We need FDA to be appropriate and flexible; we need it to be engaged. We need it to be supported by equally engaged CDC and NIH efforts to provide the science and surveillance to assure that we are on the path to better health in America.

Thank you for the opportunity to testify. I will be pleased to contribute to this important process in any way.